## REMARKS

Claims 34-36 and 46-48 are pending in this application. Claim 34 is amended, without prejudice or disclaimer, by deleting the terms "less than" and "purified" for clarity. Claim 36 is amended to recite "rabbit kidney cells." The amendments are fully supported by the specification as discussed herein. Therefore, no new matter is introduced. The Office Action is discussed below:

***Claim Rejection under 35 USC § 112:***

On pages 2-3 of the office action, the examiner has rejected claims 34-36 and 46-48 under 35 U.S.C. 112, first paragraph, allegedly for reciting "purified soy hydrolysate at a concentration of about 0.05% (w/v) to less than about 1% (w/v). The examiner alleges that the specification does not provide sufficient support for the limitation "about 0.05% (w/v) to less than about 1% (w/v)."

Applicants respectfully disagree with the examiner and refer to the specification, for example, page 3 [13], wherein it is clearly described that "[t]he soy hydrolysate can be present in a concentration of at least 0.05% (w/v) ....., the soy hydrolysate can be present in a concentration of less than 1.0% (w/v) ....., the soy hydrolysate can be present in a concentration of between about 0.2% (w/v) to about 0.6% (w/v) ...., the soy hydrolysate can be present in a concentration of between about 0.25% (w/v) to about 0.35% (w/v) and ..... the soy hydrolysate can be present in a concentration of about 0.3% (w/v) ...."

Applicants also refer to the specification, for example, page 4 [14], wherein it is clearly described that the "medium comprising soy hydrolysate at a concentration of about 0.05% (w/v) to about 1% (w/v)...."

Therefore, the limitation "about 0.05% (w/v) to less than about 1% (w/v)" is fully supported by the specification and no new matter is introduced. However, in order to expedite the prosecution, applicants amend claim 34, without prejudice or disclaimer, by deleting the term "less than" for clarity.

On pages 3-4 of the office action, the examiner has rejected claims 34-36 and 46-48 under 35 U.S.C. 112, second paragraph, allegedly as being indefinite for the

recitation of "0.05% (w/v)", "1% (w/v)", and "0.3% (w/v)". In response, applicants clarify that the solutions are made as described in the specification, for example, see the Examples as described on pages 17 through 22. Applicants further clarify that a solution made from 1 gram of hydrolysate, in 1 liter (1000 ml) of liquid (water or buffer) is intended to be a 0.1% (w/v) solution, as noted by the examiner. Therefore, the intended metes and bounds of the claim are clear to one skilled in the art.

On page 4 of the office action, the examiner has rejected claim 34 and by dependence claims 35, 36, and 46-48 allegedly as being indefinite for recitation of "purified soy hydrolysate." Applicants respectfully disagree with the examiner and submit that the "purified soy hydrolysate" refers to "soy hydrolysate" as disclosed throughout the specification. See for example, page 9 at paragraphs [30] and [31], page 15 at paragraph [47], and page 18 at paragraphs [57] and [58]. However, in order to expedite the prosecution, applicants amend claim 34, without prejudice or disclaimer, by deleting the term "purified."

Regarding the written description issues raised by the examiner, applicants also refer to the dictates of the MPEP (See MPEP § 2111, Rev. 5, August 2006) that:

> During patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification. "The Federal Circuit's *en banc* decision in *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005) expressly recognized that the USPTO employs the "broadest reasonable interpretation" standard....

In view of the above, applicants submit that the claims, as written and/or amended, are fully supported by the specification, as discussed above. Therefore, withdrawal of the rejection is solicited.

***Claim Rejection under 35 USC § 103:***

On pages 5-7 of the office action, the examiner has rejected claims 34-36 and 46-48 allegedly as being unpatentable over Shibuya *et al.* (US Patent No. 6,406,909) in view of Kistner *et al.* (US Patent No. 5,753,489), Quest International Product Information, Norwich, NY, 1995 and Sheffield Pharma.

On pages 7-11 of the office action, the examiner has maintained the rejection of claims 34-38 and 46-48 allegedly as being unpatentable over Price *et al.* (WO 98/15614) in view of Kistner *et al.* (US Patent No. 5,753,489), Quest International Product Information, Norwich, NY, 1995 and Sheffield Pharma.

According to the examiner, Shibuya *et al.* or Price *et al.* disclose a method of culturing animal cells using serum-free medium or components from animals (refers to Shibuya col. 2 lines 56-65; and Price pages 2 and 24), animal cells may be mammalian cells such as CHO, HeLa, BHK, myeloma (refers to Shibuya col 4 lines 42-48), and the soy hydrolysate may be Hysoy (refers to Shibuya col. 8, lines 14-22). The examiner admits that Shibuya *et al.* do not disclose the method steps of infecting the cells with a virus, incubating the cells to propagate the virus, and harvesting the virus or virus antigen produced, and particular sizes of the molecules in the hydrolysates according to the claimed invention. However, the examiner believes that Kistner *et al.*, Quest International Product Information and the technical literature from Sheffield Pharma can rectify the deficiencies of Shibuya *et al.* and Price *et al.*

Applicants respectfully disagree with the examiner and reiterate the dictates of MPEP § 2111 that:

During patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification." The Federal Circuit's *en banc* decision in *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005) expressly recognized that the USPTO employs the "broadest reasonable interpretation" standard:

> The Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art." *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364[, 70 USPQ2d 1827] (Fed. Cir. 2004). Indeed, the rules of the PTO require that application claims must "conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear

> support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description." 37 CFR 1.75(d)(1).

See MPEP § 2111, Rev. 5, August 2006 at 2100-37.

In this case, applicants point out that the claimed methods avoid animal proteins, whereas the media disclosed by Shibuya *et al.* and Price *et al.* employ animal proteins The instant specification clearly describes that the:

> medium that is not supplemented with proteins and protein components from higher multicellular non-plant eukaryotes (that is, vertebrates), that possess the secondary, tertiary and quaternary structures characteristic of the proteins as they occur in nature. Typical proteins that are avoided are those found in serum and serum derived substances, such as albumin, transferrin, insulin and other growth factors. Recombinantly-produced versions of animal proteins, which can contain immunogenic bacterial components, also are avoided according to the invention, and are not present in the animal protein free medium of the invention.

See specification, for example, paragraph [28] bridging pages 7 and 8. As such, no animal proteins are added for the purposes of cell growth or maintenance.

In contrast, the basal medium of Shibuya *et al.* and Price *et al.* contains "animal proteins" according to the instant definition of "animal proteins." More specifically, Shibuya *et al.* basal medium "include various peptide hormones and growth factor proteins that are not directly separated from animals, i.e., those which are produced with recombinant techniques...." A list of various nutrient components added to the serum-free medium of Shibuya *et al.* as basal medium components are listed in Table 1, which also include "Insulin Human Recombinant" (see Shibuya *et al.* col. 5-6, Table 1, more specifically, col. 5, lines 23-27 and col. 6, line 33). Accordingly, Shibuya adds animal proteins for the purposes of cell growth or maintenance.

Likewise, Price *et al.*'s basal medium also contains insulin, cytokines and various growth factors (see Price *et al.*, for example, page 13, lines 5 to 23, and Table 1). It is further clarified that the complete media is prepared by mixing the basal medium with

other plant extracts such as soy hydrolysate (see Price *et al.*, for example, page 18, lines 13 to 25). Accordingly, Price adds animal proteins for the purposes of cell growth or maintenance.

Therefore, Shibuya *et al.* and Price *et al.* do not disclose the claimed invention. In contrast to the prior art, Applicants need not add animal proteins for the purposes of cell growth or maintenance.

Applicants point out that any medium prepared based on Shibuya or Price's basal medium would contain animal proteins for cell growth or maintenance. Kistner *et al.* (US Patent No. 5,753,489), Quest International Product Information, and/or the technical literature from Sheffield Pharma, do not rectify the deficiencies of Shibuya *et al.* and Price *et al.*, as discussed above. Therefore, a combination of Shibuya and/or Price and Kistner, Quest International Product Information and/or the technical literature from Sheffield Pharma does not make the claimed inventions obvious.

In view of the above, applicants request the withdrawal of the obviousness rejection.

***Miscellaneous:***

Applicants note that claim 36 is missing the recitation of "rabbit kidney cells", among other cell types, as described in the specification (see for example, page 16 paragraph [51]). Accordingly, applicants amend the claim to add the missing cell type. Therefore, no new matter is introduced.

Applicants also note that on page 1 at 1) & 6) and presumably on 5, line 1, of the Office Action, the examiner has entered claims '36-38' instead of '34-36'. In this response to the Office Action, applicants refer to claims '34-36' instead of claim '36-38'. Appropriate correction/acknowledgement by the examiner is required for the record.

## REQUEST

Applicants submit that claims 34-38 and 46-48 are in condition for allowance, and respectfully request favorable consideration to that effect. The examiner is invited to contact the undersigned at (202) 416-6800 should there be any questions.

Respectfully submitted,

August 7, 2007

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